

REMARKS

Claims 1-6, 12, 15, 16, 43, 47-48, 59-61, 140-146, 174-176 and 186-188 are pending in this application. Claims 144-146 have been cancelled without prejudice or disclaimer. Claims 140-143 and 174-176 have been withdrawn by the examiner. Claims 1-6, 12, 15, 16, 43, 47-48, 59-61, and 186-188 are currently under examination. Claims 186, 187, and 188 are new and dependent of claim 1, 43, and 59, respectively. New claims are fully supported by the specification (see for example, pages 17-18). Applicants amend the independent claims 1, 43, and 59 to recite hybrid medical implant, and amend step b) of the claims to recite "irradiating the interlocked hybrid material to crosslink...." for clarity as discussed herein. Support for the amendment can be found throughout the specification, for example, see pages 4-7, 13-14, Example 1, and original claims 1, 43, and 59. Therefore, no new matter is introduced. The Office Action is discussed below:

Obviousness Rejection and Response to Arguments:

On pages 2-9 of the Office Action, the examiner has maintained the obviousness rejection of the claims as described below:

On pages 2-5 of the Office Action, the examiner rejects Claims 1-4, 6, 12, 15, 16, and 59-61 under 35 U.S.C. 103(a) allegedly as being unpatentable over Merrill *et al.* (PN 5,879,400) in view of Ashby *et al.* (PN 5,989,472).

On pages 5-6 of the Office Action, the examiner rejects Claims 43 and 48 under 35 U.S.C. 103(a) allegedly as being unpatentable over Merrill *et al.* in view of Ashby *et al.* and Johnson (PN 4,971,761).

On page 7 of the Office Action, the examiner rejects Claim 5 under 35 U.S.C. 103(a) allegedly as being unpatentable over Merrill *et al.* in view of Ashby *et al.* as applied to claim 1 above, and further in view of Kagiya *et al.* (PN 3,894,928).

On pages 7-8 of the Office Action, the examiner also rejects Claim 5 under 35 U.S.C. 103(a) allegedly as being unpatentable over Merrill *et al.* in view of Ashby *et al.* as applied to claim 1 above, and further in view of Patel (PN 4,164,458).

On pages 8-9 of the Office Action, the examiner rejects Claim 47 under 35 U.S.C. 103(a) allegedly as being unpatentable over Merrill *et al.* in view of Ashby *et al.* and Johnson as applied to claim 43 above, and further in view of Patel.

On pages 9-10 of the Office Action the examiner provides response to the arguments, filed on March 24, 2010.

In the response filed on March 24, 2010, applicants submitted that the teachings of Merrill are different from the teachings of the present application with regards to heating a previously irradiated piece. The examiner asserted that Merrill teaches both heating of the material to above the melting temperature and radiation of the material to crosslink. The examiner concludes that barring a showing of unexpected results, it would have been obvious to one of ordinary skill in the art at the time the invention was made to radiate then heat the material of Merrill as opposed to simultaneous heating and irradiation, because both are known process steps taught by Merrill and would be a rearrangement of known process steps.

Applicants respectfully disagree with the examiner and submit, even if the cited references are combined, would not result in the claimed methods or the products made by the claimed methods. Applicants point out that the examiner has not addressed how a combination of the cited references teach or suggest all claim limitations of the independent claims 1, 43 or 59. Thus, all independent claims and the claims depending therefrom are nonobvious over the cited references, as mandated in the MPEP that:

"All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).

See MPEP §2143.03 at 2100-142 (Rev. 6, September 2007).

The examiner also has not addressed how a rearrangement of known process steps satisfies:

Not only must all of the elements recited in the claim be present, the elements must be "arranged or combined in the same

way" as recited in the claim in order for anticipation to be found.
Net Money/IN Inc. v. VeriSign Inc., 545 F.3d 1359, 1369-71, 88
USPQ2d 1751, 1758-59 (Fed. Cir. 2008).

Also, it is not addressed by the examiner, how a combination of cited references, even if the steps are rearranged would yield the claimed process and the products made by the process.

In order to assist the examiner in further distinguishing the claimed invention from the cited references and any combinations thereof, as asserted by the examiner, applicants provide the following clarification regarding the independent claims 1, 43 and 59:

The invention according to claim 1 relates to a method of making a hybrid medical implant comprising "hybrid material" made by compression molding of polyethylene powder to a piece; irradiating the interlocked hybrid material to crosslink the hybrid material to form a strong interface between the polyethylene and the piece; and heating the hybrid material above the melting point of the radiation crosslinked polyethylene.

The invention according to claim 43 relates to a method of forming and sterilizing a hybrid medical implant comprising "hybrid material" as recited in claim 1 and sterilizing the hybrid medical implant with a gas.

Claim 59 also relates to a hybrid medical implant comprising "hybrid material" made by the method as recited in claim 1.

As asserted by the examiner, Merrill discloses crosslinked materials and Ashby discloses molding of polyethylene powder to a metal piece. The examiner speculated that a combination of the two references would yield the claimed process and the products made by the process. Applicants draw the examiner's attention to the currently amended step b) of claims 1, 43, and 59 that recites:

"b) irradiating the interlocked hybrid material to crosslink the compression molded polyethylene portion of the hybrid material by ionizing radiation, thereby forming a strong interface between the polyethylene and the piece".

That is, the process involves irradiation of a hybrid material or a hybrid medical implant to "form a strong interface between the polyethylene and the piece". A combination of cited references does not teach irradiation of a "hybrid material" nor a hybrid medical implant. Thus, a simple combination of pre-crosslinked material with a metal piece does not teach the claimed process and does not form the claimed product having a strong interface between the polyethylene and the piece.

Again, Johnson's sterilization of a product made by combining Merrill and Ashby would not teach a process of sterilizing and forming a "hybrid medical implant". Because, such sterilization does not cover sterilization of the strong interface of the hybrid materials made by the claimed process, as clarified above.

Regarding claim 5, applicants refer to above clarification that Kagiya and/or Patel do not rectify the deficiencies of Merrill and Ashby. Therefore, any combination of the cited references would not make the claimed invention obvious.

However, in order to expedite the prosecution and for additional clarity, applicants amend the independent claims 1, 43, and 59 to recite the hybrid medical implant and the step b) to recite "irradiating the interlocked hybrid material to crosslink...." Support for the amendment can be found throughout the specification, for example, see pages 4-7, 13-14, Example 1, and original claims 1, 43, and 59. As described in the specification, "mechanically interlocked" refers generally to interlocking of polyethylene and the counterface, that are produced by various methods, including compression molding, heat and irradiation, thereby forming an interlocking interface. The specification also defines, "Components of a device having such an interlocking interface can be referred to as a "hybrid material"." (see specification, for example, see pages 13-14).


As clarified above, even if the cited references are combined, would not disclose the claimed methods of making a hybrid medical implant by crosslinking hybrid materials nor would result in a product made by the claimed methods.

Therefore, in view of the above clarifications and amendments to the claims, applicants request withdrawal of the obviousness rejection.

REQUEST

Applicants submit that claims 1-6, 12, 15, 16, 43, 47, 48, 59-61, and 186-188 are in condition for allowance, and respectfully request favorable consideration to that effect. The Examiner is invited to contact the undersigned at (202) 628-6600 should there be any questions.

Respectfully submitted,



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Date

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